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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,693	05/26/2000	Masaya Yamanouchi	20-4710P	9841

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EXAMINER	
COOK, LISA V	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/578,693	**Applicant(s)** YAMANOUCHI ET AL.	
	Examiner Lisa V. Cook	**Art Unit** 1641	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *2,4,6,9,16-19,21-24 and 27*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

LONG V. LE 10/27/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

Request for Reconsideration

1. Applicant's response and re-submitted Declaration to the Office Action mailed June 13, 2006 is acknowledged (paper filed 10/4/06). Currently claims 2, 4, 6, 9, 16-19, 21-24 and 27 are currently pending and under examination.

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 2, 4, 6, 16, 17, 18, 22, 23, 24, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and Simon et al. (The Journal of Biological Chemistry, 272(16) 4/18/97, 10652-10663).

Gorski et al. disclose a comparative study evaluating the increased concentration of fatty acid binding protein (FABP) concentrations in plasma samples of patients with chronic renal failure. Plasma FABP concentration was measured by a sensitive noncompetitive sandwich ELISA. PAGE 194 2nd column. Urine measurements of increased FABP are taught on page 193, 3rd column.

Plasma FABP concentration is shown to markedly increase in patients with chronic renal failure. Page 194, 3rd column. The findings suggest that the kidney plays a dominant role in the clearance of plasma FABP. Page 194 3rd column.

Gorski et al. differ from the instant invention in not specifically teaching the detection of liver-type fatty acid binding protein.

However, Maatman et al. identified the liver-type fatty acid binding protein utilized in the instant invention. Page 285, 1st column. This is supported by Applicants arguments (page 24 of the response filed 9/14/01 in paper #7). Maatmann et al. discloses liver-type fatty acid binding proteins and speculates that it is utilized in nephrotoxicity. Maatman et al. teaches that L-FABP and H-FABP were found in the kidney (found in kidney tissue). See page 289.

While, Simon et al. teach that the liver fatty acid binding protein functions to suppress expression in the proximal nephron (kidney tissue). See abstract and page 10655.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the liver-type fatty acid binding protein as taught by Maatmann et al., having proven function is the kidney (nephron) as taught by Simon et al. to detect the specific kidney diseases relating to FABP in the method of Gorski et al. because both Maatman and Simon taught that L-FABP was located in the kidney and Maatman et al. taught that "the liver-type

FABP binds various ligands and may be involved in the renal excretion of exogenous and endogenous metabolites. The liver-type FABP also binds some drugs and may in this way prevent nephrotxicity". Page 289, 2nd column 1st paragraph. While, Simon et al. demonstrated that the liver fatty acid binding protein [heptad repeat] mediate suppression in the stomach, liver, and kidney and represents a target for identifying transcription factors that regulate gene expression. See page 10662-1st column-last paragraph.

II. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and Simon et al.(The Journal of Biological Chemistry, 272(16) 4/18/97, 10652-10663) and further in view of Kimura et al. (Journal of Biological Chemistry, 3/25/91, Vol.266., No.9., pages 5963-5972).

See discussion of Gorski et al. in view of Maatman et al. and Simon et al. as set forth above.

Gorski et al. in view of Maatman et al. and Simon et al. differ from the instant invention in failing to teach that the liver-type FABP is found in the proximal tubule of the kidney and does not cross-react with a heart muscle-type fatty acid binding protein.

However, these characteristics of α_{2U}-globulin were already known in the prior art. Specifically Kimura et al. disclose that fatty acid-binding proteins found in the kidney could be distinguished according to their primary structure and histologic distribution. Two specific FABPs weighing 14 and 15.5 kDa were found in male rat kidney cytosol.

The 14 kDa compound was identified as heart FABP and localized in the cytoplasm of the epithelia of the kidney distal tubules. The 15.5 kDa compound was identified as a proteolytically modified form of α_{2U}-globulin (alpha 2u-globulin) and localized in the endosomes or lysosomes of kidney proximal tubules.

Gorski et al. in view of Maatman et al. and Simon et al. and in further view of Kimura et al. are all analogous art because they are from the same field of endeavor, both inventions teach methods involving FABP detection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the antibody which would not cross-react with a muscle-type fatty acid binding protein as taught by Kimura et al., to detect the specific kidney FABP in the method of Gorski et al. in view of Maatman et al. and Simon et al. because such antibodies as taught by Kimura et al. are well known in the art.

A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such antibody assays, because Kimura et al. had already taught that the kidney contained two different types of fatty acid binding proteins, one designated the heart-FABP and the other designated the kidney-FABP. (page 5964, Results).

One having ordinary skill in the art would have been motivated to distinguish between the two types by employing an antibody that would not cross react with the other type (heart-FABP/kidney distal tubules) in order to receive an accurate, more precise measure of the concentration of the FABP of interest (in this case kidney-FABP/ kidney proximal tubules).

III. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and Simon et al.(The Journal of Biological Chemistry, 272(16) 4/18/97, 10652-10663) and further in view of Galaske et al. (Pflugers Archives European Journal of Physiology, 1978, 375,3, 269-277-ABSTRACT ONLY).

Please see previous discussions of Gorski et al. in view of Maatman et al. and Simon et al.

Gorski et al. in view of Maatman et al. and Simon et al. differ from the instant invention in not teaching a detection system involving a chronic renal disease (anti-GMB-nephritis model) further monitoring specimen collection at various intervals.

Galaske et al. disclosed the glomerular filtration and tubular uptake of plasma proteins in the acute heterologus phase of an anti-GMB nephritis model. Injections of anti-glomerular-basement membrane serum (anti-GMB-serum) were evaluated in tubular reabsorption and tubular flow at various times. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a anti-GMB nephritis model as taught by Galaske et al., to detect kidney diseases via proteins in the method of Gorski et al. in view of Maatman et al. and Simon et al. because Galaske et al. disclose that such models existed allowing for protein detection in plasma and urine.

One of ordinary skill in the art would have been motivated to do this in order to detect renal disorders at the onset and follow the disease progression/regression.

Response to Arguments

3. Applicant's arguments filed October 4, 2006 have been fully considered but they are not persuasive.

Declarative Evidence

Applicants contend that the Declaration of record filed 3/20/06 and executed by Dr. Takeshi Sugaya (March 14, 2006) is important since the subject matter achieves unexpected superior results compared with the prior art. However, the fact that the results obtained in making the claimed change in the prior art method are unexpectedly good is not controlling on the patentability where making such a change would be obvious to one skilled in the art. *In re Szumski* (CCPA 1962) 302 F2d 753, 133 USPQ 551. In the case, the prior art detects L-FABP and H-FABP in kidney tissue [See references to Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and Simon et al.(The Journal of Biological Chemistry, 272(16) 4/18/97, 10652-10663)] while the correlation of FABPs to kidney disease is taught by Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195). not disclose or suggest the claimed element of diagnosing or prognosing kidney disease and the assertion that L-FABP and H-FABP as equivalent compounds is improper.

Therefore it is maintained that it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the liver-type fatty acid binding protein as taught by Maatmann et al., having proven function is the kidney (nephron) as taught by Simon et al. to detect the specific kidney diseases relating to FABP in the method of Gorski et al. because both Maatman and Simon taught that L-FABP was located in the kidney and Maatman et al. taught that "the liver-type FABP binds various ligands and may be involved in the renal excretion of exogenous and endogenous metabolites. The liver-type FABP also binds some drugs and may in this way prevent nephrotxicity". Page 289, 2nd column 1st paragraph. While, Simon et al. demonstrated that the liver fatty acid binding protein [heptad repeat] mediate suppression in the stomach, liver, and kidney and represents a target for identifying transcription factors that regulate gene expression. See page 10662-1st column-last paragraph.

One of ordinary skill in the art at the time of applicant's invention would have been motivated to replace the H-FABP of Gorski et al. with the L-FABP taught by Maatman et al. and Simon et al. because the two types of FABP (heart and liver) were both found in the kidney and suggested to have utility in kidney functions.

Further, the use of a known member of a class of materials (FABPs located in the kidney) in a process is not patentable if other members of the class were known to be useful for that purpose, even though the results are better than expected. *Mills et al. v. Watson, Comr. Pats.* (CADC 1955) 223 F2d 335, 105 USPQ 355.

4. For reasons aforementioned, no claims are allowed.

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Art Unit 1641
Remsen 3C-59
October 20, 2006